K082934 1/1

EXTREMITY MEDICAL

APR 23 2009

510k Summary of Safety and Effectiveness

Extremity Medical Implant System

Submitter:	EXTREMITY MEDICAL LLC 300 Interpace Parkway Suite 410 Parsippany, NJ 07054
Contact Person	Jamy Gannoe President Phone: (973) 588-8980 Email: jgannoe@extremitymedical.com
Date Prepared	April 13, 2009
Trade Name	EXTREMITY MEDICAL Midfoot Screw System
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Product Code	HWC
Predicate Devices	1. 3.5 Fully Threaded Screw , Synthes K050683 2. EXTREMITY MEDICAL Compression Screw K081934 3. Pioneer Medical, Stayfuse K022726 4. 6.5 Midfoot Fusion Bolt, Synthes K081071
Device Description	The EXTREMITY MEDICAL Midfoot Screw System
Indications for use	The Extremity Medical Midfoot Screw System is intended for fixation arthrodesis of the metatarsal-cuneiform, navicular-cuneiform, metatarsal-cuboid, talonavicular, and calcaneocuboid joints.
Statement of Technological Comparison	The EXTREMITY MEDICAL Midfoot Screw System and its predicate devices have the same indications for use; have a similar design; are made of similar materials, and have equivalent mechanical properties.
Conclusion	The EXTREMITY MEDICAL Midfoot Screw System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, materials, design, test data and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2009

EXTREMITY MEDICAL LLC
% Mr. Jamy Gannoe
300 Interpace Parkway, Suite 410
Parsippany, NJ 07054

Re: K082934
Trade/Device Name: EXTREMITY MEDICAL Midfoot Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 13, 2009
Received: April 14, 2009

Dear Mr. Gannoe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXTREMITY MEDICAL

Indications for Use

510(k) Number (if known): K082934

Device Name: EXTREMITY MEDICAL Midfoot Screw System

Indications for Use:

"The Extremity Medical Midfoot Screw System is intended for fixation arthrodesis of the metatarsal-cuneiform, navicular-cuneiform, metatarsal-cuboid, talonavicular, and calcaneocuboid joints"

Prescription Use X AND/OR Over-the-counter _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082934

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